

REMARKS

Claims 1-9, 11-16, 18-24, 26, 27, and 29-31 are pending in the present application.

Claim Rejections under 35 USC § 103

Claims 1-9, 11-13, 18-23 and 30-31

Claims 1-9, 11-13, 18-23 and 30-31 are rejected under 35 USC. § 103(a) as being unpatentable over EP 0904729 (herein after the “EP publication”) in view of US 7,045,359 (herein after “Birks et al.”) together further in view of US 7,192,782 (hereinafter “Roller et al.”).

In determining that the claimed subject matter is obvious, the Examiner states that “[i]t would have been within the skill of the art to further modify over EP 0904729 in view of Birks et al. together further in view of Roller et al. and create the claimed different flow rates using a flow rate controller to gain the above advantages.” Office Action of August 8, 2008, at page 3. Applicant respectfully asserts that a *prima facie* obviousness rejection requires more than technical feasibility for a combination of features from cited references.

With respect to the Examiner’s stated combination, Applicant asserts that modifying the analyzer of the EP publication to provide a flow rate to the NO sensor that is lower than the exhalation flow rate would impermissibly alter the principle of operation of the analyzer and render device of the EP publication unsatisfactory for its intended purpose. MPEP 2143.01(VI) entitled, “The Proposed Modification Cannot Change the Principle of Operation of a Reference,” and MPEP 2143.01(V) entitled, “The Proposed Modification Cannot Render the Prior Art Unsatisfactory for its Intended Purpose,” are directly applicable to the present rejection. Applicant respectfully directs the Examiner’s attention to the cases cited within those sections, *In re Gordon* and *In re Ratti*, respectively.

In comparison to the present application’s disclosure and the pending claims, the analyser disclosed in the EP publication is primarily focused on converting all of NO to NO₂ by increasing

the pressure throughout the system. Specifically, the system increases the pressure in two stages. Herein, the Examiner is referred to Figure 2 which depicts two pumps (*i.e.*, pump 30 and pump 36) that successively compress the gas in order for the gas to enter the measuring chamber (46) where NO is converted to NO₂. This is supported in the specification in paragraph [0020] where it is disclosed that the pressurising means can be one or a plurality of pumps, connected in series, which successively compress the gas in one or more stages. This is further supported in paragraph [0027] which teaches that the volume of the second pump (36) is much smaller than the volume of the first pump (30), so that the gas sample is compressed when it fills the second reciprocating pump (36). The ratio between the volumes is selected according to the pressure increase desired and the positive pressure available in the first control gas line (32). The large difference in volume causes a large pressure differential and, thus, more rapid conversion of NO into NO₂. For example, paragraph [0049] describes achieving a pressure of 10 Bars. Finally, compression of the gas sample increases the rate of reaction in the chemical reaction of NO and O₂, and virtually all the NO in the gas sample is converted into NO₂. In summary, the EP analyzer is based on successively increasing pressure, so as to allow for the measurement of NO₂ as a surrogate for NO, as its principle of operation.

The rationale for this principle of operation, centered on increasing the pressure, is clear. The inventors of the EP publication, finding that NO is a difficult gas to measure¹, designed an analyzer with a principle of operation premised on increasing the pressure of a sample gas and measuring NO₂ as a surrogate for NO. Accordingly, pressure is deliberately increased so as to convert NO “almost completely” to NO₂, thereby addressing the inventors’ stated concerns about the volatility of NO and allowing for the use of NO₂ as a measurement surrogate.² Modifying the EP publication so as to provide the sensor with a sample at flow rate lower than the exhalation flow rate would be

¹ “However, NO is not a very easy gas to measure. And, as noted above, NO is converted into NO₂ when it comes into contact with O₂, thereby affecting determination of the patient’s uptake of NO.” The EP publication at paragraph [0007].

² “Instead of attempting to measure NO content directly and compensate the measurement or determination for the formation of NO₂... the conversion of NO is accelerated, and the end concentration of NO₂ is determined instead.” The EP publication at paragraph [0011] and [0012].

counter to its basic principle of operation and render the analyzer of the EP publication unsuitable for NO measurement, as NO₂ could no longer be used as a surrogate for NO.

Accordingly, Applicant asserts that the Examiner's stated modifications to the EP publication to provide a flow rate to the sensor that is lower than the exhalation flow rate are not only non-obvious, but are also counter-intuitive to one of skill in the art in view of the EP publication's requirement for increasing the pressure of the sample. Applicant respectfully requests that the rejections of claims 1-9, 11-13, 18-23 and 30-31 under 35 USC. § 103(a) be withdrawn.

Claims 14-15, 26-27 and 29

Claims 14-15, 26-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 in view of Birks et al. together further in view of Roller et al (U.S. Patent No.: 7,192,782) as applied to claims 1-9, 11-13, 18-23 and 30-31 above, and further in view of Holowko et al.

Applicant respectfully requests that the rejections of claims 14-15, 26-27 and 29 be withdrawn for the reasons stated above. Briefly, modifying the analyzer of the EP publication to employ a flow rate to the sensor that is lower than the exhalation flow rate would be contrary to the analyzer's principle of operation based on increasing pressure and render the analyzer unsuitable for measuring NO because the analyzer relies on the near complete conversion of NO to NO₂, which allows for the measurement of NO₂ as a surrogate for NO.

Claims 16 and 24

Claims 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0904729 in view of Birks et al. together further in view of Roller et al (U.S. Patent No.: 7,192,782) as applied to claims 1-9, 11-13, 18-23 and 30-31 above, and further in view of Oswin et al.

Applicant respectfully requests that the rejections of claims 16 and 24 be withdrawn for the reasons stated above.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No.: 03-1952** referencing **Docket No.: 514862000700**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 19, 2008

Respectfully submitted,

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